

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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COMMUNICATION FROM ISO (report of activities relevant to Codex work)

1. The International Organization for Standardization (ISO) has prepared this information paper as part of on-going updates and communications between the Codex Alimentarius Commission (CAC) Secretariat and the ISO Central Secretariat. It provides a summary of current work undertaken by ISO that may be of interest to the CAC and has the intent to support and enhance dialogue and coordination between the two organizations.

International Organization for Standardization (ISO)

2. ISO is the International Organization for Standardization (<http://www.iso.org/>). ISO is a non-governmental organization established in 1947 with members consisting of the leading and recognized national standards organizations of 156 countries, on the basis of one member per country.

3. ISO has a Central Secretariat, based in Geneva, Switzerland, that employs approximately 150 staff. However, most of the work in developing and maintaining the portfolio of some 15 600 technical International Standards is shared amongst the membership, with individual national members providing and financing the Chairmanships and Secretariats for one or more of the 192 technical committees and 541 subcommittees managing some 2,200 working groups.

4. Two policy committees of ISO, DEVCO and COPOLCO, identify and monitor actions and programmes to encourage and facilitate the participation, respectively of developing countries and consumer interests, in standardization. A third policy committee of ISO, CASCO, deals with conformity assessment matters and its work is discussed and updated later in greater detail.

International Standards

5. While the most well known standard in the ISO portfolio is ISO 9001:2000, *Quality management systems — Requirements*, the great majority of ISO standards do not relate to management system requirements. Rather they include terminology, sampling, test and analytical methods, interoperability as well as specifications and performance requirements for industrial and agricultural products, equipment, processes and, to a growing extent, services.

6. Application of the international standards that ISO produces starts out as being voluntary. In a majority of cases these standards are needed and used voluntarily as references within commercial contracts between market players, for example in procurement contracts or as a basis for companies to develop, test and market their products.

7. However, more and more standards are cited by regulators to provide a means of compliance with their technical regulations. This is recommended in the WTO TBT and SPS agreements so as to reduce technical barriers to trade, and, for example, by the United Nations Economic Commission for Europe (UNECE) and the Asia Pacific Economic Cooperation Subcommittee on Standards and Conformance (APEC SCSC), in the context of implementing good regulatory practices.

ISO's international status

8. ISO also has specific status with many UN agencies, including the WHO and FAO, and is an observer to the Codex Alimentarius Commission (CAC). It is also an observer at the WTO Committee on Trade and Environment (CTE), the Committee on Technical Barriers to Trade (WTO TBT), and the Committee on Sanitary and Phytosanitary Measures (SPS). In the area of technical assistance, ISO cooperates regularly with WTO and ITC, and has entered into a Memorandum of Understanding with UNIDO.

9. ISO's observer status to the CAC provides an opportunity for the coordination of issues related to a variety of ISO standards that are adopted and used by Codex in its work. According to the second edition of Volume 13, *Codex Alimentarius Methods of Analysis and Sampling, 1994*, ISO Committees with Standards adopted by Codex include: ISO/TC 34, *Food products* (310 Standards); ISO/TC 147, *Water quality* (19 Standards); ISO/TC 47, *Chemistry* (5 Standards), and 1 Standard in each of ISO/TC 24, *Sieves and other sizing methods*, ISO/TC 61, *Plastics* and ISO/TC 93, *Starch*. This list is also complemented by Codex's adoption of the CASCO Standard ISO/IEC 17025 for testing and calibration laboratories.

10. Although there are many ISO Committees with work affecting Codex, the priority areas of mutual interest on which ISO would like to maintain and nurture dialogue with the CAC are the work of ISO/TC 34 on food products and the generic work of the ISO Committee on conformity assessment (ISO/CASCO).

CODEX and ISO Cooperation

11. There is a long history of collaboration between the Codex Committees and ISO/TC 34, *Food products*. ISO/TC 34 supports establishing an on-going and sustainable framework for collaboration between Codex and ISO, in order to enhance the mutual coordination of work and the elimination of duplication and contradictions.

12. Codex and ISO activities are complementary. Codex, as a governmental organization, prepares documents to assist governments in their statutory and regulatory work to protect their citizens from health hazards caused by food consumption. ISO, as a non-governmental organization, prepares standards on test methods to assist stakeholders along the whole food chain to fulfil both the statutory and regulatory requirements, as well as the requirements of consumers of these products.

13. In 2005, ISO/TC 34 published ISO 22000, *Food safety management systems — Requirements for any organization in the food chain*. It is based on a management systems approach as in ISO 9001:2000, as well as the Codex hazard analysis and critical control point (HACCP) system. The necessity for a new ISO International Standard was justified by the diversity of national standards (Danish, Dutch, Australian, Irish, etc.) that have been developed as well as retailer organizations have prepared documents (BRC, EFSIS, IFS, etc.) for the establishment and auditing of food safety systems, possibly including HACCP requirements. ISO 22000 should help to clarify and harmonize the present situation. Codex took an active part in the development of ISO 22000.

14. According to a survey, more than 50 countries are in the process of adopting and translating ISO 22000 into their own language (among them 28 European countries as ISO 22000 was prepared in parallel with the European Committee for Standardization - CEN). ISO 22000, and its associated conformity assessment, should have a positive impact on the harmonization and proper implementation of voluntary and mandatory food import and export requirements, inspection and certification systems.

15. Several Working Groups have been established under the direct responsibility of TC 34 for the development of important horizontal standards:

WG 7 on *Genetically modified organisms and derived products*, with AFNOR, France as convenor.

WG 8 on *Food safety management systems (FSMS)*, with DS, Denmark, as convenor.

WG 9 on *Traceability system in the agriculture food chain*, with UNI, Italy, as convenor.

WG 10 on *Food irradiation*, with IRAM, Argentina, as convenor.

WG 11 on *Requirements for bodies providing audit and certification of FSMS*, with DS, Denmark, as convener.

WG 12 on *Guidance on the application of ISO 9001 in agriculture*, with ANSI, USA, as convener.

16. WG 7 standards, developed in close cooperation with CEN, are as follows:

ISO 21571:2005, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Nucleic acid extraction*

ISO 21569:2005, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid based methods*

ISO/TS 21098:2005, *Foodstuffs — Nucleic acid based methods of analysis of genetically modified organisms and derived products — Information to be supplied and procedure for the addition of methods to ISO 21569, ISO 21570 or ISO 21571*

ISO 21570:2005, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Quantitative nucleic acid based methods*

ISO 24276:2006, *Foodstuffs — Nucleic acid based methods of analysis for the detection of genetically modified organisms and derived products — General requirements and definitions*

17. WG 8 prepared ISO 22000 and also ISO/TS 22004, *Food safety management systems — Guidance on the application of ISO 22000:2005*, which was published in 2005. This Technical Specification explains the process approach used in ISO 22000. For an organization to function effectively and efficiently, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, is considered as a process. Often the output from one process directly forms the input to the next. ISO/TS 22004 gives generic guidance for small and large enterprises on the implementation of ISO 22000.

18. WG 9 is working on ISO 22005, *Traceability in the feed and food chain — General principles and basic requirements for system design and implementation*. The traceability of food products "from the farm to the fork" is an important requirement. ISO 22005 will be a useful tool to prove the origin of food. It is intended to complement the Codex work on traceability as it explains the design of a suitable system to help food producers and manufacturers to comply with the relevant statutory and regulatory requirements set by Codex. It has been circulated as a Draft International Standard. The voting period ended on 2006-04-19.

19. WG 10 was established in 2005 and is working on ISO 22008, *Food irradiation — Good processing practices for the irradiation of foods intended for human consumption*. This standard specifies the good processing practices for the irradiation of foods intended for human consumption (development, validation and routine control requirements). It is applicable to food products processed by gamma rays, X-rays or electron beams for the purpose of inhibition of germination of bulbs, tubers and root crops, phytosanitary treatment, delay of ripening of fruits and vegetables, reduction of microbial load and insect infestation, control of foodborne pathogens, sterilization of foodstuffs for immunocompromised patients, and shelf life extension for perishable foods in general. This standard is presently at the Committee Draft stage.

20. The need for an International Standard containing requirements for bodies providing audit and certification of food safety management systems against ISO 22000 arose. However, to develop such a standard, the assistance of ISO/CASCO and its liaison organizations, in particular the International Accreditation Forum (IAF), was needed. Therefore, a joint working group with ISO/CASCO (WG 11) was established for the elaboration of ISO/TS 22003, *Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems*. This is based on the generic standard that covers the area of certification and auditing of management systems, namely, ISO/IEC 17021, *Conformity assessment — Requirements for bodies providing audit and certification of management systems*, and includes specific guidance on certification to ISO 22000. It is still at a draft stage but it is hoped it will be published in the second half of 2006.

21. WG 12 is developing ISO 22006, *Guidelines on the application of ISO 9001:2000 for crop production*. This standard contains the text of ISO 9001 and adds additional requirements for agricultural production operators and for documents associated with a Farm Plan. It is currently an Accepted Work Item.

22. With regard to analytical and test methods, in the field of milk and milk products, ISO/TC 34/SC 5 and the International Dairy Federation (IDF) work together to prepare analysis methods that are published jointly. Most of these analysis methods are taken into account by the Codex Commodity Committee on Milk and Milk Products and are endorsed by the Codex Committee on Methods of Analysis and Sampling. Important new work is ISO/TS 22964:2006, *Milk and milk products — Detection of Enterobacter sakazakii*. This bacterium has been found to exist in some infant formulations. The bacterium is thermotolerant and can remain after sterilization.

23. ISO/TC 34/SC 9 develops horizontal methods for the enumeration of such contaminants as *Salmonella*, *Escherichia coli*, *Bacillus cereus*, thermotolerant *Campylobacter* and pathogenic *Vibrio*, and the use of polymerase chain reaction (PCR) for the detection of food-borne pathogens. AOAC International has accepted the ISO *Salmonella* test method as an AOAC Official Method of Analysis.

24. ISO/TC 34 will continue to offer its full support and cooperation to the Commission with a view to avoiding duplication of work and it will adopt, for its own documents, the conclusions of the Commission on all matters concerning food hygiene requirements.

ISO's conformity assessment standards and their use in food safety

25. ISO is an international standards developer. It does not undertake assessments of conformity of products, management systems, processes or services against the requirements of the standards it produces.

26. ISO does however produce International Standards and Guides on how assessment of conformity should take place - this is the role of the ISO Policy Committee on Conformity Assessment ([ISO/CASCO](#)). It is this body within ISO that is closest to covering the same subject matter as the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS).

27. As a consequence, ISO can be viewed as providing both international standards that relate to the characteristics of specific products, as well as providing generic horizontal standards that document agreed procedures for the assessment of conformity (e.g. testing, inspection and certification) of products and processes.

28. In relation to ISO/CASCO, most of the conformity assessment Guides have been or are in the process of being turned into International Standards. Annex 1 gives a list of recently completed, or nearly completed documents.

Conclusion

29. It is recognized that the Commission's members, as governments, have the authority to regulate at the national level and that ISO, as a producer of voluntary international standards, does not. In the framework of good regulatory practice, as promoted at international and regional levels, international standards and guides may be considered useful by regulators as effective and efficient tools to achieve important regulatory mandates, manage risk and address market confidence.

30. ISO considers that by using its international standards, regulatory authorities will achieve their aims in public health and safety at less cost to manufacturers, consumers and the taxpayer. Using international standards also assists countries to meet their WTO TBT and SPS Agreement obligations.

31. For any further information on technical developments within ISO that have been reported in this paper, please do not hesitate to contact the following individuals:

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Annex 1**Recent ISO/IEC International Standards and Guides
on Conformity Assessment**

In relation to ISO/CASCO, most of the conformity assessment Guides have been or are in the process of being turned into International Standards. In particular, the following recently completed, or nearly completed documents may be of interest to the Commission:

- ISO/IEC 17000:2004, *Conformity assessment - Vocabulary and general principles*
- ISO/IEC Guide 60:2004, *Conformity assessment - Code of Good Practice*
- ISO/IEC Guide 68:2002, *Arrangements for the recognition and acceptance of conformity assessment results*
- ISO/IEC Guide 67:2004, *Conformity assessment - Fundamentals of product certification*
- ISO/IEC Guide 28:2004, *Conformity assessment - Guidance on a third-party certification system for products*
- ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*
- ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection* (Reconfirmed in 2002)
- ISO/IEC 17024:2003, *Conformity assessment - General requirements for bodies operating certification of persons*
- ISO/IEC FDIS 17021, *Conformity assessment -- Requirements for bodies providing audit and certification of management systems*
- ISO/IEC 17011:2004, *Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies*
- ISO/IEC 17040:2005, *Conformity assessment -- General requirements for peer assessment of conformity assessment bodies and accreditation bodies*